



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0148]

Draft Guidance for Industry on Complicated Urinary Tract Infections: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Complicated Urinary Tract Infections: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of complicated urinary tract infections (cUTIs). Specifically, this guidance addresses FDA’s current thinking regarding the overall drug development program for the treatment of cUTIs, including clinical trial designs to support approval of drugs.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Joseph G. Toerner,
Center for Drug Evaluation and Research,
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10903 New Hampshire Ave.,
Bldg. 22, rm. 6244,
Silver Spring, MD 20993-0002,
301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Complicated Urinary Tract Infections: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors and investigators in the development of drugs for the treatment of cUTIs. This draft guidance revises and replaces the draft guidance for industry entitled “Complicated Urinary Tract Infections and Pyelonephritis--Developing Antimicrobial Drugs for Treatment” published in 1998.

Infections of the urinary tract occurring in patients with underlying functional or anatomic abnormalities of the urinary tract are defined as cUTIs. Infections of the kidney, called

pyelonephritis, can occur in persons without underlying abnormalities of the urinary tract, but are also considered to be a subset of cUTI. Different types of bacteria can cause cUTI, but Gram-negative bacteria are most often associated with cUTI.

This draft guidance includes recommendations for an efficacy endpoint and noninferiority trial design. The efficacy endpoint, based on resolution of clinical symptoms and eradication of bacteria from the urinary tract, was derived from previously conducted trials for the treatment of cUTI. The draft guidance provides a scientific justification for a noninferiority margin based on historical observational data compared to the results of previously conducted clinical trials. The draft guidance also provides a discussion about patients with unmet need who have an infection caused by bacterial pathogens that show resistance to most antibacterial drugs on in vitro susceptibility testing.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively. The collections of information referred to in the guidance for clinical trial sponsors

“Establishment and Operation of Clinical Trial Data Monitoring Committees” have been approved under OMB control number 0910-0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.